Claims 1-66 are indicated as pending in the subject application, of which claims 23-54, 56-62 and 68 are indicated as being withdrawn from consideration. Applicants would note that in the Response dated February 26, 2003, Applicants had instructed that claims 23-41 were to be canceled without prejudice. Claims 1-13, 15-21, 55 and 63-65 stand rejected under 35 U.S.C. §103. Claims 14 and 22 were objected to as depending from a rejected base claim, however, the Examiner indicated that the claims would be allowable if appropriately re-written in independent form.

Claims 1 and 55 were amended as follows. Notwithstanding that Applicants believe that the pending claims are distinguishable from, and patentable over, the cited prior art, Applicants have amended each of claims 1 and 55 as had been suggested by the Examiner and to advance prosecution. More particularly, each of claims 1 and 55 were amended so as to more distinctly claim an aspect of the present invention, namely that the insertion of the entry alignment device into the eye is accomplished without an incision being provided in the conjunctiva or the sclera. The amendments to the claims are supported by the originally filed disclosure.

The Office Action includes a requirement that formal drawing figures that incorporate the proposed drawing changes contained in an amendment dated December 23, 2002 should be submitted concurrent with the present Response. In this regard, and in anticipation of the approval of the previously filed drawing amendment, Applicants had filed formal drawings reflecting incorporation of the proposed changes under a Transmittal of Formal Drawing dated February 26, 2003, which transmittal was acknowledged as being received by the USPTO on March 4, 2000. As such, further action is not believed required, as satisfaction of the Examiner's requirement has been satisfied by this prior submission. However, if the Examiner determines that such drawing figures

were not received or, if received, need to be re-submitted, then the Examiner is respectfully requested to contact the undersigned.

Included herewith is a marked-up version of the amendments to the subject application by the current amendment. The marked-up versions are found on the pages captioned or entitled "Details of Amendments" that follow the signature page of the within Response.

35 U.S.C. §103 REJECTIONS

Claims 1-13, 15-21, 55 and 63-65 stand rejected under 35 U.S.C. § 103 as being unpatentable over the cited prior art for the reasons provided on pages 3-6 of the above-referenced Office Action. Because claims were amended in the foregoing amendment, the following discussion refers to the language of the amended claim(s). However, only those amended features specifically relied on in the following discussion shall be considered as being made to overcome the prior art reference. The following addresses the specific rejections provided in the above-referenced Office Action.

CLAIMS 1-12, 55 & 63

Claims 1-12, 55 and 63 stand rejected as being unpatentable over Peyman [USP 5,487,725] in view of Skolik et al. (USP 5,817,099; "Skolik") for the reasons provided on page 3-4 of the above referenced Office Action. Applicants respectfully traverse.

Applicant claims, claim 1, a method for providing access within an eye during an ocular surgical procedure, which method includes providing an entry alignment device that is configured

so as to provide an entry aperture in each of the conjunctiva and sclera of the eye and maintaining the entry aperture in each of the conjunctiva and sclera aligned during the surgical procedure. Such a method also includes inserting the entry alignment device into the eye so as to form the entry apertures. As indicated hereinabove, claim 1 was amended to further provided that the step of inserting is accomplished without an incision in the conjunctiva or the sclera as had been suggested by the Examiner. As indicated herein, Applicants so-amended claims 1 and 55 to advance prosecution of the subject application, however, such amendment was made without prejudice to filing a continuing application to continue prosecution of pending claims 1 and 55.

As was indicated in Applicants' remarks included with Applicants' Response dated December 17, 2002, Peyman discloses the known technique of making a *sclerotomy incision* (i.e., an incision in the sclera) and inserting a probe through the sclerotomy incision into the vitreous cavity. As is known to those skilled in the art, to make this incision in the sclera the conjunctiva is first dissected or pulled back to expose the sclera. It also might be possible to make a large incision in the conjunctiva so as to expose the sclera sufficiently to make the required sclerotomy incision. Peyman also nowhere makes reference to, nor suggests, an entry alignment device. As such, Peyman does not disclose, suggest or teach, explicitly or inherently, the transconjunctival methodology claimed by Applicants.

In addition, it has been previously indicated by Applicants in the prior filed Response that in contrast to the claimed invention Skolik describes a methodology whereby an *incision* is made in the eye sufficiently sized so as to receive the port/ seal device disclosed therein (see column 10, lines 30-48 thereof). More specifically, Skolik describes the use of the disclosed port/ seal device

in connection with cataract surgery, where such an incision is made in the anterior segment or globe of the eye that includes the cornea. In the method disclosed in Skolik, an incision is first required to be made in the eye to gain access to the interior of the anterior segment and then the port/seal device is inserted into the incision made in the eye. Also because an incision is made before insertion of the port/seal device, Skolik cannot disclose inserting the entry alignment device that is configured as claimed by Applicants into the eye *so as to form the entry apertures* as is claimed by Applicants because the incision made according to the method disclosed in Skolik forms the entry aperture. In other words, Skolik does not disclose a technique for trans-conjunctival insertion of an entry alignment device as is set forth in the claims. Give the size and construction of the device disclosed in Skolik, it also is practically speaking not possible to construct a device that could be used in a transconjunctival insertion procedure without an incision. It thus necessarily follows, that it cannot be hardly said that one skilled in the art would have been motivated by the teachings of Skolik as is suggested in the Office Action so as to yield the methodology of the present invention.

In sum, each of the cited references describes a methodology in which an incision is made in the eye prior to insertion of the surgical instruments (Peyman) or the port/ seal device of Skolik. As is known to those skilled in the art, making an incision in the sclera of the posterior segment involves the dissection or pulling back of the conjunctiva prior to expose the sclera. Thus, none of the cited references can explicitly or inherently disclose the method of claim 1 in which both the conjunctiva and the sclera are traversed and penetrated by the entry alignment device. In addition, Peyman and Skolik alone or in combination do not teach or suggest the method of the present invention. Moreover, there is no teaching, suggestion or motivation offered in either of the cited

references to modify the methodology disclosed in the primary reference, Peyman, so as to yield either of the methodologies claimed by Applicants.

It is respectfully submitted that the foregoing arguments, also apply to distinguish claim 55 and the claims that depend respectively from either of claims 1 or 55 from the cited combination of references.

It is respectfully submitted that claims 1-12, 55 and 63 are patentable over the cited reference(s) for the foregoing reasons.

CLAIMS 13, 15-21, 64 & 65

Claims 13, 15-21, 64 and 65 stand rejected as being unpatentable over Peyman in view of Skolik and further in view of Saperstein et al. (USP 5,919,158; "Saperstein) for the reasons provided on pages 4-6 of the above referenced Office Action. Applicants respectfully traverse.

Claims 13, 15-24, 64 and 65 depend respectively from one of claims 1 or 55. As indicated above, Peyman and Skolik alone or in combination do not disclose, teach or suggest the methods as set forth in either of claims 1 or 55. Moreover, there is no teaching, suggestion or motivation offered in either of the cited references to modify the methodology disclosed in the primary reference, Peyman, so as to yield either of the methodologies claimed by Applicants. As such, each of claims 13, 15-21, 64 and 65 are considered to be in allowable form at least because of their dependency from an independent claim that is considered to be allowable. As to the tertiary reference, Saperstein, Applicants make the following observations.

Saperstein is used in the grounds for the rejection for the limited purpose of teaching the use of a light source to illuminate an area. Saperstein, however, also describes the known technique of inserting surgical instruments/ cannulas/ light probe through a sclerotomy (i.e., *sclerotomy incision*) in the eye. Thus, Saperstein does not disclose, teach or suggest the transconjunctival methodology claimed by Applicants. Moreover, there can be no teaching, suggestion or motivation offered in the tertiary cited reference to modify the methodology disclosed in the primary reference, Peyman, so as to yield either of the methodologies claimed by Applicants.

In sum, each of the cited references describes a methodology in which an incision is made in the eye prior to insertion of the surgical instruments (Peyman and Saperstein) or the port/ seal device of Skolik. As is known to those skilled in the art, making an incision in the sclera of the posterior segment involves the dissection or pulling back of the conjunctiva prior to expose the sclera. Thus, none of the cited references can explicitly or inherently disclose the methods as set forth in claims 1 or 55 in which both the conjunctiva and the sclera of an eye are traversed and penetrated by the entry alignment device. In addition, Peyman and Skolik alone or in combination do not teach or suggest the methods of the present invention. Moreover, there is no teaching, suggestion or motivation offered in any of the cited references to modify the methodology disclosed in the primary reference, Peyman, so as to yield either of the methodologies of claims 1 and 55 claimed by Applicants.

It is respectfully submitted that claims 13, 15-24, 64 and 65 are patentable over the cited reference(s) for the foregoing reasons.

The following additional remarks shall apply to each of the above.

Assuming, arguendo, that Peyman and Skolik, alone or in combination with Saperstein, teach what is suggested in the Office Action, Applicants assert that the 35 U.S.C. § 103 rejection of the claims is still improper because the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). In order to make out a prima facie case of obviousness, there must exist in the cited references some suggestion or teaching to combine the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat App. & Inter. 1993). Moreover, the references must contain an indication that the resultant combination will be reasonably successful.

As provided in the foregoing remarks, the cited references do not teach or suggest the features of the provided entry alignment device claimed by Applicant. Further, the cited references do not teach or suggest the combination of steps of the method claimed by Applicants. In addition, there is no suggestion anywhere in these references that such a combination would be reasonably successful.

The Federal Circuit has indicated in connection with 35 U.S.C. §102 that in deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify *corresponding elements* disclosed in the allegedly anticipating reference (emphasis added, citations in support omitted). *Lindemann Maschinenfabrik GMBM v. American Hoist and Derrick Company et al.*, 730 F. 2d 1452, 221 USPQ 481,485 (Fed. Cir. 1984). Notwithstanding that the instant rejection is under 35

U.S.C. §103, in the present case the Examiner has not shown that the devices and method steps in any of the cited references corresponds, as that term is used above by the Federal Circuit, in any fashion to the provided entry alignment devices and methodology in their entire claimed form as set forth in any of claims 1, 13 and 55 of the present invention.

As provided in MPEP 2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F. 2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F. 2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). As provided above, the references cited, alone or in combination, include no such teaching, suggestion or motivation.

It is respectfully submitted that for the foregoing reasons, claims 1-13, 15-21, 55 and 63-65 are patentable over the cited reference(s) and satisfy the requirements of 35 U.S.C. §103. As such, these claims are allowable.

CLAIMS 14 & 22

As indicated above, claims 14 and 22 were objected to as depending from a rejected base and that these claims would be allowable if appropriately re-written in independent form.

In as much as Applicants believe that the base claim, claim 55, is allowable and/ or the intervening claim 13-14 also are separately allowable Applicants have not re-written claims 14 and 22 as suggested by the Examiner. Applicants, however, reserve the right to later amend any claims

14 and 22 so as to be in independent form or to add one or more independent claims including the limitations of any of claims 14 and 22.

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Applicants believe that additional fees are not required for consideration of the within Response. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,
Edwards & Angell, LLP

Date: June 11, 2003

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DETAILS OF AMENDMENTS

Please amend the subject application as follows:

IN THE CLAIMS

Amend claims 1 and 55 to read as follows:

1. (TWICE AMENDED) A method for providing access within an eye during an ocular surgical procedure, comprising the steps of:

providing an entry alignment device that is configured so as to provide an entry aperture in each of the conjunctiva and sclera of the eye and maintaining the entry aperture in each of the conjunctiva and sclera aligned during the surgical procedure; and

inserting the entry alignment device into the eye so as to form the entry apertures, where said inserting is accomplished without an incision in the conjunctiva or the sclera.

55. (AMENDED) A method for treating a posterior segment of an eye comprising the steps of:

providing a plurality of entry alignment devices, each entry alignment device being configured so as to provide an entry aperture in each of the conjunctiva and sclera of the eye and maintaining the entry aperture in each of the conjunctiva and sclera aligned during the surgical procedure;

inserting each of the plurality of entry alignment devices into the eye, where said inserting is accomplished without an incision in the conjunctiva or the sclera; and

implementing a corrective procedure for the retina.